



PATENT
Attorney Docket No. DHI-03864

1644
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James L. Brown
Serial No.: 09/539,735
Filed: 03/30/00
Entitled: DIAGNOSIS OF AUTOIMMUNE DISEASE

Group No.: 1644
Examiner: P. Nolan

TRANSMITTAL LETTER

U.S. Patent and Trademark Office
Box Sequence, PO Box 2327
Arlington, VA 22202

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Sir or Madam:

Enclosed please find a Supplemental Information Disclosure Statement, Form PTO-1449 and copy of 20 references for filing in the U.S. Patent and Trademark Office.

The Commissioner is hereby authorized to charge any fee or credit overpayment related to this filing to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: June 3, 2004

Mahattamdan
Maha A. Hamdan
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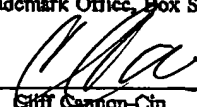
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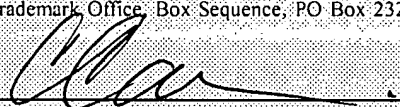
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Entitled: **DIAGNOSIS OF AUTOIMMUNE DISEASE**

**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

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Sir or Madam:

The citations listed below, copies attached, were cited in the Declaration by Dr. Kohn that was mailed to the Office on May 12, 2004. These citations may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

- U.S. Patent No. 4,608,341 issued 8/26/86 to Ambesi-Impiombato;
- Di Cerbo *et al.* (1999) "Signaling pathways involved in thyroid hyperfunction and growth in Graves' disease," *Biochimie* 81:415-24;
- Taskén *et al.* (2004) "Localized Effects of cAMP Mediated by Distinct Routes of Protein Kinase A," *Physiol. Rev.* 84:137-167;
- Saji *et al.* (1991) "Insulin and Insulin-Like Growth Factor-I Inhibit Thyrotropin-Increased Iodide Transport in Serum-Depleted FRTL-5 Rat Thyroid Cells: Modulation of Adenosine 3',5'-Monophosphate Signal Action," *Endocrinology* 128:1136-1143;

- Khan *et al.* (1995) "Arachidonic Acid and Free Fatty Acids as Second Messengers and the Role of Protein Kinase C," *Cell. Signal.* 7:171-184;
- Leemhuis *et al.* (2002) "The Protein Kinase A Inhibitor H89 Acts on Cell Morphology by Inhibiting Rho Kinase.," *J. Pharmacol. Exp. Ther.* 300:1000-1007;
- Davies *et al.* (2000) "Specificity and mechanism of action of some commonly used protein kinase inhibitors," *Biochem. J.* 351:95-105;
- Cross *et al.* (1995) "Wortmannin and Its Structural Analogue Demethoxyviridin Inhibit Stimulated Phospholipase A₂ Activity in Swiss 3T3 cells; Wortmannin Is Not a Specific Inhibitor of Phosphatidylinositol 3-kinase," *J. Biol. Chem.* 270:25352-25355;
- Vlahos *et al.* (1994) "A Specific Inhibitor of Phosphatidylinositol 3-Kinase, 2-(4-Morpholinyl)-8-phenyl-4H-1-benzopyran-4-one (LY294002)," *J. Biol. Chem.* 269:5241-5248;
- Garcia *et al.* (2002) "PI3K is Involved in the IGF-I Inhibition of TSH-Induced Sodium/Iodide Symporter Gene Expression," *Mol. Endocrinol.* 16: 342-352;
- Marcocci *et al.* (1987) "Norepinephrine and Thyrotropin Stimulation of Iodide Efflux in FRTL-5 Thyroid Cells Involves Metabolites of Arachidonic Acid and is Associated with the iodination of thyroglobulin," *Endocrinology* 120:1127-1133;
- Kohn *et al.* (1997) "Characterization of Monoclonal Thyroid Stimulating and Thyrotropin Binding-Inhibiting Autoantibodies from a Hashimoto's Patient Whose Children had Intrauterine and Neonatal Thyroid Disease," *J. Clin. Endocrinol. Metab.*, 82:3998-4009;
- Sarlis, *et al.* (1997) "Graves' Disease Following Thyrotoxic Painless Thyroiditis. Analysis of Antibody Activities Against the Thyrotropin Receptor in Two Cases," *Thyroid* 7:829-836;
- Wortsman *et al.* (1998) "Thyrotropin Receptor Epitopes Recognized by Graves' Autoantibodies Developing under Immunosuppressive Therapy," *J. Clin. Endocrinol. Metab.* 83:2302-2308;

PATENT

Attorney Docket No. **DEI-03864**

- Adams *et al.* "The Assessment of Thyroid Function by Tracer Tests with Radioactive Iodine," New Zealand Med. J., pp 36-41;
- McKenzie (1958) "The Bioassay of Thyrotropin in Serum," *Endocrinol.* 372-382;
- Kriss *et al.* (1964) "Isolation and Identification of the Long-Acting Thyroid Stimulator and Its Relation to Hyperthyroidism and Circumscribed Pretibial Myxedema," *J. Clin. Endo. and Metab.* 24:1005-1028;
- Inui *et al.* (1998) "Increase of Thyroid Stimulating Activity in Graves' Immunoglobulin-G by High Polyethylene Glycol Concentrations Using Porcine Thyroid Cell Assay," *Thyroid* 8:319-325;
- Minich *et al.* (2004) "A Coated Tube Assay for the Detection of Blocking Thyrotropin Receptor Autoantibodies," *J. Clin. Endocr. Metab.* 89:352-356; and
- Davies *et al.* (1998) "Thyroid Stimulating Antibodies Predict Hyperthyroidism," *J. Clin. Endocr. Metab.* 83:3777-3781.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: June 3, 2003

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FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: DHI-03864		Serial No.: 09/539,735	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))				Applicant: James L. Brown			
				Filing Date: 03/30/00		Group Art Unit: 1644	
U.S. PATENT DOCUMENTS							
Examiner Initials	Serial / Patent No.	Issue Date	Applicant / Patentee		Class	Subclass	Filing Date
	1	4,608,341	Ambesi-Impiombato				
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)							
	2	Di Cerbo <i>et al.</i> (1999) "Signaling pathways involved in thyroid hyperfunction and growth in Graves' disease," <i>Biochimie</i> 81:415-24					
	3	Taskén <i>et al.</i> (2004) "Localized Effects of cAMP Mediated by Distinct Routes of Protein Kinase A," <i>Physiol. Rev.</i> 84:137-167					
	4	Saji <i>et al.</i> (1991) "Insulin and Insulin-Like Growth Factor-I Inhibit Thyrotropin-Increased Iodide Transport in Serum-Depleted FRTL-5 Rat Thyroid Cells: Modulation of Adenosine 3',5'-Monophosphate Signal Action," <i>Endocrinology</i> 128:1136-1143					
	5	Khan <i>et al.</i> (1995) "Arachidonic Acid and Free Fatty Acids as Second Messengers and the Role of Protein Kinase C," <i>Cell. Signal.</i> 7:171-184					
	6	Leemhuis <i>et al.</i> (2002) "The Protein Kinase A Inhibitor H89 Acts on Cell Morphology by Inhibiting Rho Kinase.," <i>J. Pharmacol. Exp. Ther.</i> 300:1000-1007					
	7	Davies <i>et al.</i> (2000) "Specificity and mechanism of action of some commonly used protein kinase inhibitors," <i>Biochem. J.</i> 351:95-105					
	8	Cross <i>et al.</i> (1995) "Wormannin and Its Structural Analogue Demethoxyviridin Inhibit Stimulated Phospholipase A ₂ Activity in Swiss 3T3 cells Wormannin Is Not a Specific Inhibitor of Phosphatidylinositol 3-kinase," <i>J. Biol. Chem.</i> 270:25352-25355					
	9	Vlahos <i>et al.</i> (1994) "A Specific Inhibitor of Phosphatidylinositol 3-Kinase, 2-(4-Morpholinyl)-8-phenyl-4H-1-benzopyran-4-one (LY294002)," <i>J. Biol. Chem.</i> 269:5241-5248					
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	11	Marcocci <i>et al.</i> (1987) "Norepinephrine and Thyrotropin Stimulation of Iodide Efflux in FRTL-5 Thyroid Cells Involves Metabolites of Arachidonic Acid and is Associated with the iodination of thyroglobulin," <i>Endocrinology</i> 120:1127-1133					
	12	Kohn <i>et al.</i> (1997) "Characterization of Monoclonal Thyroid Stimulating and Thyrotropin Binding-Inhibiting Autoantibodies from a Hashimoto's Patient Whose Children had Intrauterine and Neonatal Thyroid Disease," <i>J. Clin. Endocrinol. Metab.</i> , 82:3998-4009					
	13	Sarlis, <i>et al.</i> (1997) "Graves' Disease Following Thyrotoxic Painless Thyroiditis. Analysis of Antibody Activities Against the Thyrotropin Receptor in Two Cases," <i>Thyroid</i> 7:829-836					
	14	Wortsman <i>et al.</i> (1998) "Thyrotropin Receptor Epitopes Recognized by Graves' Autoantibodies Developing under Immunosuppressive Therapy," <i>J. Clin. Endocrinol. Metab.</i> 83:2302-2308					
	15	Adams <i>et al.</i> "The Assessment of Thyroid Function by Tracer Tests with Radioactive Iodine," <i>New Zealand Med. J.</i> , pp 36-41					
	16	McKenzie (1958) "The Bioassay of Thyrotropin in Serum," <i>Endocrinol.</i> 372-382					
	17	Kriss <i>et al.</i> (1964) "Isolation and Identification of the Long-Acting Thyroid Stimulator and Its Relation to Hyperthyroidism and Circumscribed Pretibial Myxedema," <i>J. Clin. Endo. and Metab.</i> 24:1005-1028					
	18	Inui <i>et al.</i> (1998) "Increase of Thyroid Stimulating Activity in Graves' Immunoglobulin-G by High Polyethylene Glycol Concentrations Using Porcine Thyroid Cell Assay," <i>Thyroid</i> 8:319-325					
	19	Minich <i>et al.</i> (2004) "A Coated Tube Assay for the Detection of Blocking Thyrotropin Receptor Autoantibodies," <i>J. Clin. Endocr. Metab.</i> 89:352-356					
	20	Davies <i>et al.</i> (1998) "Thyroid Stimulating Antibodies Predict Hyperthyroidism," <i>J. Clin. Endocr. Metab.</i> 83:3777-3781					
Examiner:				Date Considered:			
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							